

Appl. No. 09/899,552  
Response dated November 30, 2005  
Reply to Office Action of June 30, 2005

### REMARKS/ARGUMENTS

#### Specification Amendments

By the present amendment, the specification at page 18, line 24, has been amended to add the term "restraint" to the list of possible stresses. Support for this amendment is found in claim 6 of the application as filed as permitted by MPEP 608.01(I).

The specification has also be amended to add, at page 20, line 6, that it is a further embodiment of the invention that negative changes in antibody responses during stress are multiplied with a co-efficient greater than 1, for example, with a coefficient of about 1.5. Support for this amendment is found in claims 4 and 5 of the application as filed, as permitted by MPEP 608.01(I).

The Applicants submit that no new matter has been added to the specification by the present amendments and that the amendments are fully supported by the application as filed. Entry of the specification amendments is respectfully requested.

#### Claim Amendments

By the present amendment, claims 2, 3 and 21 have been rewritten so that they depend on claim 1 and claim 22 has been rewritten so that it depends on claim 3. In light of the above amendments, any duplicated subject matter in the newly dependent claims has removed. The Applicant submits that these amendment are made to reduce the number of independent claims and in no way alters the scope of the previous claims.

Claim 11 has been amended to insert the SEQ ID NO for the sequence tyrosine-glutamine-alanine-lysine and to replace the term "glycine" with "glutamine" which corrects an obvious typographical error. Support for this latter amendment is found on page 16, line 29.

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Previous claims 25-38 have been cancelled.

Claims 39-52 are new and are directed to the method of the present invention that includes an immunization with both an antigen (as in claims 1-24) and another antigen that can evoke a cell-mediated immune response (CMIR), a measurement of both an antibody response and a CMIR and a combination of both of these responses to rank the immune response of the animal. Specific support for new claim 39 is found on page 20, lines 6-14, of the application as filed and in previous claim 25. Support for new claim 40 is found on page 25, lines 12-14, of the application as filed and in previous claim 26. Support for new claims 41 and 42, is found on page 21, lines 14-24, of the application as filed and in previous claims 27 and 28. Support for new claim 43 is found on page 20, line 18, of the application as filed and in previous claim 29. Support for new claim 44 is found on page 20, lines 20-21, of the application as filed and in previous claim 30. Support for new claim 45 is found on page 20, lines 22-23, of the application as filed and in previous claim 31. Support for new claim 46 is found on page 16, lines 14-18, of the application as filed and in previous claim 32. Support for new claim 47 is found on page 26, lines 16-18, of the application as filed and in previous claim 33. Support for new claim 48 is found on page 26, lines 18-19, of the application as filed and in previous claim 34. Support for new claim 49 is found on page 26, lines 20-21, of the application as filed and in previous claim 35. Support for new claim 50 is found on page 25, line 3, to page 26, line 15, of the application as filed and in previous claim 36. Support for new claim 51 is found on page 18, lines 27-29, of the application as filed and in previous claim 37. Support for new claim 52 is found on page 19, lines 2-7, of the application as filed and in previous claim 38.

Claims 1-24 and 39-52 are pending in the present application.

The claim amendments have been made without prejudice and without acquiescing to any of the Examiner's objections. The Applicants submit that no new

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matter has been entered by the present amendment and entry of the amendments is respectfully requested.

The Official Action dated June 30, 2005 has been carefully considered. It is believed that the claims submitted herewith and the following comments represent a complete response to the Examiner's comments and place the present application in condition for allowance. Reconsideration is respectfully requested.

The Examiner's objections will be addressed in the order in which they appear in the Office Action.

2. The Examiner maintains that the restriction requirement issued on March 22, 2005, is proper and has therefore made the requirement final. The Applicants have elected, with traverse, Group I (claims 1-24). The Examiner's argues that "there are many examples of prior art where animals were tested for antibody response to rank immune responders without being concomitantly tested for cell mediated immune responses, so a prior art search for antibody responses to rank immune responder would not uncover all art pertaining to ranking immune responders by cell mediated immunity". In response, the Applicants respectfully point out that none of the claims in the present application are directed to methods where the animals are being tested for a cell mediated immune response alone so art pertaining to ranking immune responders by cell mediated immunity" would not be relevant to the present application unless that art also taught concomitantly ranking immune responders by antibody response. In all claims in the present application, the method involves ranking either an antibody response alone, or concomitantly with a cell mediated immune response. To highlight this, the Applicants have cancelled claims 25-38, and have added new claims 39-52, which correspond in scope to claims 25-38 but have been written so that they are either directly or indirectly dependent on claim 1. While support for new claims 39-52 has been outlined in detail above, the Applicants wish to point the Examiner, in particular, to page 20, lines 6-14, of the application as filed, where the following is stated:

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According to another embodiment of the invention, the method of ranking the immune response further comprises exposing the animals of a population to an antigen, preferably under stress, which can evoke a cell mediated immune response (CMIR), measuring an indicator of the CMIR at least once during the stress and combining it with the measurement for antibody response, to obtain an immune response, wherein an immune response of a test animal that is greater than the average immune response of the population during stress indicates that the test animal is a high immune responder. [Emphasis added]

The Applicants submit therefore that the claims pending in the present application are directed to a single and distinct invention.

3. The Examiner has noted that claims 25-38 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. As explained above, the Applicants have cancelled claims 25-38 in the present amendment and have added new claims 39-52, which correspond in scope to claims 25-38 but have been written so that they are either directly or indirectly dependent on claim 1. The Applicants submit that the generic or linking claim is now claim 1 and therefore, the claims of the present application are directed to a single and distinct invention.

4. The Examiner has advised the Applicant that, should claim 1 be found allowable, claim 2 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. By the present amendment, claim 2 has been rewritten so that it is dependent on claim 1 and any duplicated subject matter in claim 2 has been removed. This amendment serves to highlight that the limitation in claim 2 that is not found in claim 1 is that the animals are immunized with at least one antigen *during the stress*. Since this limitation does not appear in claim 1, the Applicants submit that claim 2 is not a substantial duplicate of claim 1 and respectfully request that the Examiner's objection to claim 2 under CFR 1.75 be withdrawn.

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5. The Examiner has noted two informalities in claim 11, both of which have been attended to in the present amendment.

6. The Examiner has noted that the term "restraint" in claim 6 has no support in the originally filed specification. In response, the Applicants have amended the specification at page 18, line 24, to include the term "restraint" in the list of stress examples as permitted by MPEP 608.01(l). The Applicants submit that this amendment overcomes the Examiner's objection to claim 6 and they respectfully request that the objection be withdrawn.

The Examiner has further noted that in claims 4 and 5, the coefficient multiplication of 1 or 1.5 is presently disclosed for those rankings where a primary and secondary response calculation has occurred. In response, the Applicants have amended the specification at page 20, line 6, to incorporate the features of claims 4 and 5 in relation to the method as claimed in claim 3, upon which claims 4 and 5 depend, as permitted by MPEP 608.01(l). The Applicants submit that this amendment overcomes the Examiner's objection to claims 4 and 5 and they respectfully request that the objection be withdrawn.

9. The Examiner alleges that claims 1-3, 6-19 and 21 are anticipated under 35 U.S.C. §102(b) by Wagter et al. (J. Dairy Science, 1996, Vol. 79 (Suppl. 1), page 119, hereinafter Wagter). The Examiner's objection is respectfully traversed.

#### A. Summary of Wagter

Wagter describes the ranking of the immune response of 32 periparturient cows and heifers. These animals were vaccinated with *E. coli* J5 vaccine and ovalbumin (OVA) at week -8 and week -3 relative to calving and again with OVA at calving (week 0). Lymphocyte proliferation and antibody responses were determined at week -3, 0, 3 and 6 relative to calving. Wagter teaches that animals were classified based on "phenotypic variations of antibody response curve kinetics". Wagter further teaches that

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the animals were classified as either high responders (category I) or hyporesponsive, either after calving (category II) or throughout the peripartum period (category III). There is no description of the specific criteria that were used for this classification and the abstract only goes on to describe general trends when comparing antibody responses to *E. coli* and OVA, levels of total serum IgG<sub>1</sub> and disease occurrence.

**B. Wagter does not teach or suggest a method of ranking the immune response of a test animal within a population of animals under stress where the critical indicator of immune response is a change in antibody response from before the onset of stress to during the stress in the test animal compared to the change in antibody response from before the onset of stress to during the stress for the population.**

The courts have ruled that:

It is elementary that an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device. *In re Donohue*, 226 USPQ 619, 621 (Fed. Cir. 1985) citing *Dalman v. Kimberly-Clark Corp.*, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied 224 USQ 520 (1984).

There is no teaching or suggestion in Wagter to specifically look at the change that occurs in the antibody response from before the onset of stress until during the stress in the test animal and compare that value to the average change in the antibody response from before the onset of stress until during the stress in the population in order to assess a test animal's immune response. Wagter merely teaches that animals were classified based on "phenotypic variations of antibody response curve kinetics". There is no teaching of how the actual rankings could be performed and there is certainly no indication of the critical periods of time to use. Accordingly, Wagter does not teach every limitation in claim 1 or 2. With respect to claim 3, Wagter, again does not teach the critical periods of time to observe and also does not teach or suggest to add the changes in antibody responses between each measurement to provide a total

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antibody response for the test animal and compare this number to an overall total antibody response, obtained in the same manner, for the population. All of the remaining claims depend either directly or indirectly on claim 1 and, since the claim 1 is not anticipated by Wagter, claim 6-19 and 21 are likewise not anticipated.

In light of the above, the Applicants respectfully request that the Examiner's objection to claims 1-3, 6-19 and 21 under 35 U.S.C. §102(b) be withdrawn.

10. The Examiner alleges that claims 4 and 5 are anticipated under 35 U.S.C. §102(b) by CA 2,255,423 with a publication date of June 10, 2000. The Applicants submit that CA 2,255,423 is not a proper citation under any subsection of 35 U.S.C. 102. The present application is a continuation-in-part of U.S. patent application S.N. 09/215,328 (now U.S. Patent No. 6,289,564) with a filing date of December 18, 1998. CA 2,555,423 is equivalent to U.S. patent application S.N. 09/215,328 and therefore contains an identical disclosure. Since all of the teachings in CA 2,555,423 are present in U.S. patent application S.N. 09/215,328 upon which the present application claims priority, there is no manner in which CA 2,555,423 can be properly cited against any claim in the present application.

In light of the above, the Applicants respectfully request that the Examiner's objection to claims 4 and 5 under 35 U.S.C. §102(b) be withdrawn.

12. The Examiner alleges that claims 1-3, 6-12 and 14-24 are unpatentable under the judicially created doctrine of obviousness-type double patenting in light of claims 1-5 of US Patent No. 6,287,564. In response, Applicants have submitted herewith a Terminal Disclaimer in compliance with 37 CFR 1.321(c) which overcomes the Examiner's objection. Please charge the prescribed fee of \$65.00 for the filing of the Terminal Disclaimer to Deposit Account No. 02-2095. The Commissioner is hereby authorized to charge any deficiency in fees (including any claim fees) or credit any overpayment to Deposit Account No. 02-2095.

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Early and favorable action on the merits is awaited. Should the Examiner deem it beneficial to discuss the application in greater detail, the Examiner is kindly requested to contact the undersigned by telephone at (416) 957-1683 at the Examiner's convenience.

Respectfully submitted,

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